510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k042303

B. Purpose for Submission:

Assayed quality control material

C. Measurand:

Anti-HBs

D. Type of Test:

NA

E. Applicant:

Ortho-Clinical Diagnostics, Inc.

F. Proprietary and Established Names:

VITROS Immunodiagnostic Products Anti-HBs Controls

G. Regulatory Information:

1. Regulation section:

   21 CFR section 862.1660, Quality control material, assayed and unassayed.

2. Classification:

   I

3. Product code:

   JJX

4. Panel:

   Microbiology (83)

H. Intended Use:

1. Intended use(s):

   For use in monitoring the performance of the VITROS ECi/ECiQ Immunodiagnostic System when used for the quantitative *in vitro* determination of total antibody to hepatitis B surface antigen (anti-HBs) in human serum when using the VITROS Immunodiagnostic Products Anti-HBs Quantitative Reagent Pack on the VITROS ECi/ECiQ Immunodiagnostic System. The performance of the VITROS Immunodiagnostic Products Anti-HBs Controls has not been established with any other anti-HBs assays.

2. Indication(s) for use:

   For use in monitoring the performance of the VITROS ECi/ECiQ Immunodiagnostic System when used for the quantitative *in vitro* determination of total antibody to hepatitis B surface antigen (anti-HBs) in human serum.

3. Special conditions for use statement(s):

   Prescription Use

4. Special instrument requirements:

   VITROS ECi/ECiQ Immunodiagnostic System

I. Device Description:

The device is quality control material containing a measured amount of anti- HBs as determined by testing against a secondary standard calibrated against the World Health Organization's 1st International Reference Preparation, 1977. The device contains three levels of controls; nominally < 0.75 mIU/mL, 19 mIU/mL, and 289 mIU/mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   VITROS Immunodiagnostic Products Anti-HBs Controls

2. Predicate 510(k) number(s):

   k003112

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Matrix of controls	Human serum with added constituents of human origin and antimicrobial agents	Human serum with added constituents of human origin and antimicrobial agents

Differences		
Item	Device	Predicate
Intended Use	For use in monitoring the performance of the VITROS Immunodiagnostic System when used for the quantitative *in vitro* determination of total antibody to Hepatitis B surface antigen (anti-HBs) in human serum when using the VITROS Immunodiagnostic Products Anti-HBs Quantitative Reagent Pack on the VITROS Immunodiagnostic System. The performance of the VITROS Immunodiagnostic Products Anti-HBs Controls has not been established with any other anti-HBs assays.	For use in monitoring the performance of the VITROS Immunodiagnostic System when used for the qualitative *in vitro* determination of total antibody to Hepatitis B surface antigen (anti-HBs) in human serum when using the VITROS Immunodiagnostic Products Anti-HBs Reagent Pack on the VITROS ECi Immunodiagnostic System. The performance of the VITROS Immunodiagnostic Products Anti-HBs Controls has not been established with any other anti-HBs assays.
Control levels	2 positive and 1 negative	1 positive and 1 negative
Expected values	Each control has a quoted mean value derived from a minimum of 10 assays and a standard deviation anticipated for single determinations of each control in a number of different laboratories	Control is only positive or negative, no assigned values.

Differences		
Item	Device	Predicate
	using different reagent lots. Values are lot specific.	

K. Standard/Guidance Document Referenced (if applicable):

Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Draft, 1999

L. Test Principle:

NA

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

NA

b. Linearity/assay reportable range:

NA

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

World Health Organization's 1st International Reference Preparation for anti-hepatitis B surface antigen, 1977.

d. Detection limit:

NA

e. Analytical specificity:

NA

f. Assay cut-off:

NA

2. Comparison studies:

   a. Method comparison with predicate device:

   NA

   b. Matrix comparison:

   NA

3. Clinical studies:

   a. Clinical Sensitivity:

   NA

   b. Clinical specificity:

   NA

   c. Other clinical supportive data (when a. and b. are not applicable):

   NA

4. Clinical cut-off:

   NA

5. Expected values/Reference range:

   Manufacturer's product release criteria:

Control C1	≤0.75 mIU/mL
Control C2	19-32 mIU/mL
Control C3	289-479 mIU/mL

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.